

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/589,037	BUCHANAN, FRASER JAMES	
	<b>Examiner</b>	<b>Art Unit</b>	
	Angela C. Scott	1767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on April 28, 2011.
2. ☒ The allowed claim(s) is/are 1,19-21,34,36,39-41,43 and 44.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>07/01/2011</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|--|

/Mark Eashoo/  
 Supervisory Patent Examiner, Art Unit 1767

Art Unit: 1767

***Election/Restrictions***

Claims 34, 36 and 39-41 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 1, 19-21, 43 and 44, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on August 5, 2009 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Daniel Monaco on June 29, 2011.

The application has been amended as follows:

In claim 1, lines 1 and 2, "having a graded molecular weight distribution, comprising" has been substituted by --comprising an outer surface and a core, wherein the molecular weight distribution of the implant changes gradually from the outer surface to the core, the average molecular weight at the core is greater than the average molecular weight at the entire outer surface, and the rate of bioabsorbability of the core is less than the rate of bioabsorbability of the entire outer surface, said method comprising--.

Art Unit: 1767

In claim 1, lines 3 and 4, "altering the molecular weight distribution of at least a portion of the implantable substrate by exposing that portion of the implantable substrate to electron beam irradiation" has been substituted by --exposing the entire surface of the implantable substrate to electron beam irradiation to reduce the molecular weight distribution of said entire surface--.

Claim 30 is cancelled.

Claim 31 is cancelled.

Claim 32 is cancelled.

Claim 33 is cancelled.

Claim 42 is cancelled.

In claim 43, line 3, "claim 22" has been substituted by --claim 34--.

In claim 44, lines 1-3, "osteo- or rheumatoid arthritis, osteoporosis, inflammatory, neoplastic, traumatic or infectious tissue conditions, syndromes" has been substituted by --osteoarthritis; rheumatoid arthritis; osteoporosis; an inflammatory, neoplastic, traumatic or infectious tissue condition; a syndrome--.

Claim 45 is cancelled.

Claim 46 is cancelled.

Claim 47 is cancelled.

Claim 48 is cancelled.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: Independent claims 1 and 34 each require that the core of the bioabsorbable, implantable substrate have a greater average molecular weight than the entire outer surface of the substrate and that the molecular weight distribution changes gradually from the outer surface to the core. In order to accomplish this, the substrate must be rotated in relation to the electron beam or the beam must be rotated in relation to the substrate. The primary reference of Shalaby does not explicitly teach either one of these scenarios. Additionally, a Rule 1.132 Declaration was submitted on April 28, 2011 by Professor Arne Miller describing what one of ordinary skill in the art would understand by reading Shalaby. According to the declaration, Shalaby does not teach forming a molecular

Art Unit: 1767

weight gradient over the entire outer surface of the substrate where the average molecular weight is greater at the core. Additionally, this feature would not have been obvious to one of ordinary skill in the art by reading Shalaby, which is the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela C. Scott whose telephone number is (571)270-3303. The examiner can normally be reached on Monday through Friday, 8:00 am to 5:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/  
Supervisory Patent Examiner, Art Unit 1767

/A. C. S./  
Examiner, Art Unit 1767  
July 2, 2011